

(i) *Three-dose regimen.* Administer by intramammary infusion in each infected quarter as follows:

(A) *6-milliliter dose (peanut oil).* Treatment may be repeated at 12-hour intervals. Milk that has been taken from animals during treatment and for 84 hours (7 milkings) after the latest treatment must not be used for food. Animals must not be slaughtered for food during treatment or within 4 days after the latest treatment.

(B) *10-milliliter dose (sesame oil).* Treatment may be repeated at 12-hour intervals. Milk that has been taken from animals during treatment and for 60 hours (5 milkings) after the latest treatment must not be used for food. Animals must not be slaughtered for food during treatment or within 3 days after the latest treatment.

(ii) *Two-dose regimen, 10-milliliter dose (peanut oil).* Administer by intramammary infusion in each infected quarter. Treatment may be repeated at intervals of 12 hours. Milk taken from animals during treatment and for 60 hours (5 milkings) after the latest treatment must not be used for food. Animals must not be slaughtered for food during treatment or within 4 days after latest treatment.

(d) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(1) *10-milliliter dose (peanut oil).* Administer by intramammary infusion in each infected quarter. Treatment may be repeated at 12-hour intervals for not more than three doses, as indicated by clinical response.

(2) *Indications for use.* Treating bovine mastitis caused by *Streptococcus agalactiae*, *S. dysgalactiae*, and *S. uberis* in lactating cows as follows:

(3) *Limitations.* Milk that has been taken from animals during treatment and for 60 hours after the latest treatment must not be used for food. Animals must not be slaughtered for food during treatment or within 3 days after the latest treatment.

(e) *Sponsor.* See No. 010515 (sesame oil) and No. 050604 (peanut oil) in § 510.600(c) of this chapter.

(1) *NAS/NRC status.* The conditions of use were NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter,

but may require bioequivalency and safety information.

(2) *Single-dose regimen.* One 10-milliliter dose (sesame oil or peanut oil) in each infected quarter at time of drying-off.

(3) *Indications of use.* Treating bovine mastitis caused by *Streptococcus agalactiae* in dry cows.

(4) *Limitations.* Discard all milk for 72 hours (6 milkings) following calving, or later as indicated by the marketable quality of the milk. Animals must not be slaughtered for food within 14 days postinfusion.

[57 FR 37335, Aug. 18, 1992, as amended at 58 FR 500, Jan. 6, 1993]

§ 526.1696b Penicillin G procaine-dihydrostreptomycin in soybean oil for intramammary infusion (dry cows).

(a) *Specifications.* Each 10 milliliters of suspension contains penicillin G procaine equivalent to 200,000 units of penicillin G and dihydrostreptomycin sulfate equivalent to 300 milligrams of dihydrostreptomycin.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See §§ 556.200 and 556.510 of this chapter.

(d) *Conditions of use. Dairy cows—(1) Amount.* One syringe into each quarter at the last milking prior to drying off.

(2) *Indications for use.* Intramammary treatment of subclinical mastitis in dairy cows at the time of drying off, specifically against infections caused by *Staphylococcus aureus* and *Streptococcus agalactiae*.

(3) *Limitations.* Not to be used within 6 weeks of calving. For use in dry cows only. Milk taken from cows within 24 hours (2 milkings) after calving must not be used for food. Animals infused with this drug must not be slaughtered for food within 60 days of treatment nor within 24 hours after calving.

[57 FR 37336, Aug. 18, 1992]

§ 526.1696c Penicillin G procaine-dihydrostreptomycin sulfate for intramammary infusion (dry cows).

(a) *Specifications.* Each 10 milliliters of suspension contains penicillin G procaine equivalent to 1 million units of penicillin G and dihydrostreptomycin sulfate equivalent to 1 gram of dihydrostreptomycin.

(b) *Sponsor*. See No. 033392 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See §§ 556.200 and 556.510 of this chapter.

(d) *Conditions of use*. *Dairy cows*—(1) *Amount*. One syringe per quarter at the last milking prior to drying off.

(2) *Indications for use*. Intramammary use to reduce the frequency of existing infection and to prevent new infections with *Staphylococcus aureus* in dry cows.

(3) *Limitations*. Not to be used within 6 weeks of freshening. Not for use in lactating cows. Milk taken from animals within 96 hours (8 milkings) after calving must not be used for feed. Animals infused with this drug must not be slaughtered for food within 60 days from the time of infusion nor within 96 hours after calving. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37336, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992]

§ 526.1696d Penicillin G procaine-novobiocin for intramammary infusion.

(a) *Specifications*. For lactating cattle: each 10-milliliter dose contains 100,000 units of penicillin G procaine and 150 milligrams of novobiocin as novobiocin sodium. For dry cows: 200,000 units of penicillin G procaine and 400 milligrams of novobiocin as novobiocin sodium.

(b) *Sponsor*. See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Lactating cows*—(i) *Amount*. 10 milliliters in each infected quarter after milking. Repeat once after 24 hours.

(ii) *Indications for use*. Treating lactating cows for mastitis caused by susceptible strains of *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, and *Streptococcus uberis*.

(iii) *Limitations*. For udder instillation in lactating cattle only. Do not milk for at least 6 hours after treatment; thereafter, milk at regular intervals. Milk taken from treated animals within 72 hours (6 milkings) after the latest treatment must not be used for food. Treated animals must not be slaughtered for food for 15 days following the latest treatment. If redness, swelling, or abnormal milk persists,

discontinue use and consult a veterinarian.

(2) *Dry cows*—(i) *Amount*. 10 milliliters in each quarter at time of drying off.

(ii) *Indications for use*. Treatment of subclinical mastitis caused by susceptible strains of *Staphylococcus aureus* and *Streptococcus agalactiae*.

(iii) *Limitations*. For udder instillation in dry cows only. Do not use less than 30 days prior to calving. Milk from treated cows must not be used for food during the first 72 hours after calving. Treated animals must not be slaughtered for food for 30 days following udder infusion.

[57 FR 37336, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992]

§ 526.1810 Pirlimycin hydrochloride.

(a) *Specifications*. Each 10-milliliter syringe contains 50 milligrams of pirlimycin (as pirlimycin hydrochloride).

(b) *Sponsor*. See 000009 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.515 of this chapter.

(d) *Conditions of use*. (1) *Dose*. 50 milligrams in each infected quarter, repeated once after 24 hours.

(2) *Indications for use*. For lactating dairy cattle for the treatment of clinical and subclinical mastitis caused by *Staphylococcus* species, such as *Staphylococcus aureus*; and *Streptococcus* species, such as *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, and *Streptococcus uberis*.

(3) *Limitations*. Milk taken from animals during treatment and for 36 hours following the last treatment must not be used for food. Treated animals must not be slaughtered for food use for 9 days following the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[58 FR 58486, Nov. 2, 1993, as amended at 65 FR 61091, Oct. 16, 2000]

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

Sec.
529.40 Albuterol.